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(54) **AN INTRAVASCULAR STENT AND PERCUTANEOUS INSERTION SYSTEM.**

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(73) Proprietor: **Fischell, Robert E.**
1027 McCeney Avenue
Silver Spring Maryland 20901(US)

Proprietor: **Fischell, Tim A.**
362 Grant Avenue
Palo Alto California 94301(US)

(72) Inventor: **Fischell, Robert E.**
1027 McCeney Avenue
Silver Spring Maryland 20901(US)
Inventor: **Fischell, Tim A.**
362 Grant Avenue
Palo Alto California 94301(US)

(74) Representative: **UEXKÜLL & STOLBERG Patentanwälte**
Beselerstrasse 4
W-2000 Hamburg 52 (DE)

Rank Xerox (UK) Business Services
(3.10/3.6/3.3.1)

Description

This invention relates to a stent insertion apparatus, according to the preamble of claim 1. Such an apparatus is disclosed in US-A- 4 655 771

In the last decade there has been increasing use of percutaneous transluminal balloon angioplasty for the opening of stenosis of the peripheral and coronary arteries. In this procedure the uninflated balloon at the tip of the catheter is advanced into the narrowed portion of the arterial lumen. The balloon is then inflated so as to push the stenotic plaque outward thereby enlarging the luminal diameter and improving distal perfusion. The balloon is then deflated and the catheter is withdrawn from the body. Initially the blood flow at that point is typically improved to a significant degree. However, within six months, restonosis, defined as a loss of more than 50% of the initial enlargement of arterial diameter, occurs in approximately 30% of cases. It would therefore be of great value if a means could be devised to retain patency (i.e., opening) of the artery so that adequate blood flow would be maintained.

The concept of placing a coil spring intravascular stent within an artery is not new. In the September-October 1969 edition of INVESTIGATIVE RADIOLOGY, C. T. Dotter reported the insertion of 6 coil spring intravascular stents in the arteries of dogs. Three of these springs which were covered with silicone rubber occluded within 24 hours. Two out of three, bare stainless steel wire springs remained patent at $2\frac{1}{2}$ years. Dotter also described a "pusher-catheter" of equal diameter with the spring outer diameter which was used to place the springs within the artery.

In more recent work, D. Maas et al in the September 1984 edition of Radiology described improved stainless steel coil spring intravascular stents that were implanted in 65 dogs and 5 calves. a 100% success rate was reported using bare, heat treated steel alloy springs that were torqued to a reduced diameter and inserted with a special device designed for that purpose. Neither Dotter nor Maas et al were able to perform a percutaneous procedure for the stent insertion. Dotter describes a "pusher-catheter" that was of equal diameter to the outside diameter of the coil spring. Maas et al used a 7mm diameter special insertion device that applied torque to the coil spring to reduce its diameter to 7mm; i.e., the deployed outside diameter was greater than 7mm. Since the largest practical outside diameter for percutaneous delivery is less than 4mm, the device and methods used by Maas et al are not practical for percutaneous insertion.

The results of Dotter, i.e., 2 of 3 patent arteries at the end of $2\frac{1}{2}$ years using comparatively small (3.5mm) diameter coil are probably not good enough for clinical applications. The results of Maas et al were very good, but these were for inside diameters greater than 7mm.

What is really needed and not described by either Dotter or Maas et al or anyone else is a safe and simple method for percutaneous transluminal insertion of a coil spring stent whose insertion device structure allows an insertion catheter of outer diameter less than 4mm. Another requirement of the insertion device is that it maintains the reduced diameter of the coil spring stent during insertion and allows the coil to expand to a diameter greater than the diameter of the arterial lumen after removal of the insertion catheter.

To make the intravascular stent (IS) safe for human use even in small diameter coronary arteries, it is necessary for the spring material to be biocompatible and non-thrombogenic. The greatest success by Dotter and Maas et al was with bare metal coil springs. However, no investigation to date has described use of these stents in either human subjects or in animal coronary arteries. Furthermore, Dotter quotes an article which states that "It appears that success or failure of an arterial substitute in dogs bears no direct relationship to the results one will obtain when a similar substitute is used clinically for the peripheral arteries". Hence one must be concerned with the human biocompatability of the material used for the IS.

Many articles such as "ULTI Carbon Goretex: A New Vascular Graft" by R. Debski et al in the May-June 1983 edition of Current Surgery describe the superior non-thrombogenic characteristics of ultra low-temperature isotropic (ULTI) carbon as such a blood compatible material. The use of carbon as a blood compatible material for humans is well known among those skilled in the art of vascular grafts and prosthetic heart valves. However, no investigator of IS devices has ever described the use of carbon coated coil springs or carbon coated polytetrafluoroethylene (PTFE) covered coil springs to solve the problem of thrombosis of small diameter IS devices in humans.

It should be noted that nothing in the prior art describes the use of a coil spring stent for the prevention of arterial blockage due to intimal dissection (tearing away of the intima layer) following balloon angioplasty. There is approximately a 30% incidence of radiologically detectable intimal dissection following routine percutaneous transluminal coronary angioplasty (PTCA). In many of these cases this is not a problem. Vessel wall healing and remodeling typically restores a smooth luminal contour with good vessel patency within several weeks following the angioplasty. In a small but significant subset of these patients, the intimal dissection may be severe, resulting in a high risk of vessel closure within 24 hours following PTCA.

These patients will typically sustain some degree of myocardial infarction despite further aggressive attempts at revascularization, including coronary artery bypass surgery.

SUMMARY OF THE INVENTION

Thus it is an objective of the present invention to utilize a coil spring intravascular stent (IS) for the prevention of arterial restenosis.

A second objective of the invention is to utilize an IS to further enlarge the luminal diameter after successful percutaneous transluminal angioplasty.

Another objective is to provide a percutaneous transluminal catheter means for placing the IS at the appropriate place within the artery.

Still another objective is to describe a method for percutaneous insertion of intravascular stents.

Still another objective is to provide a means and method for preventing arterial blockage due to intimal dissection following balloon or other types of angioplasty.

The solution to the problems posed by the application is given by the features in the characterizing portion of claim 1.

Figs. 1A, 1B, and 1C are cross-sectional views showing respectively the shape of the plaque within an arterial wall, (A) before balloon dilation, (B) immediately after balloon dilation, and (C) at several months after dilation.

Figs. 2 is a cross-sectional view of an IS in the form of a coil spring placed in a position to prevent restenosis and/or provide additional dilation of the plaque.

Fig. 3 is a cross-sectional view of the distal end of an insertion catheter for inserting the IS.

Fig. 4 is a cross-sectional view of the proximal end of the insertion catheter.

Fig. 5 is a cross-sectional view of a wire coated with ULTI carbon.

Fig. 6 is a cross-sectional view of a wire enclosed by PTFE and coated with ULTI carbon.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1A, 1B, and 1C are cross-sectional view of an arterial wall AW surrounding a plaque P which forms an arterial stenosis or narrowing. It is well known in the art to utilize percutaneous transluminal balloon angioplasty to dilate the stenosis of Fig. 1A by expanding a balloon that is placed within the narrowed lumen. The result immediately after balloon dilation is shown in Fig. 1B. However, in approximately 30% of all balloon procedures, there is a restenosis of the artery as illustrated in Fig. 1C.

If, however, a coil spring intravascular stent (IS) 10 is placed at the dilation site immediately after balloon dilation in a position as shown in Fig. 2, the resistance of the IS 10 to deformation by inwardly directed radial pressure can preclude restenosis of the artery. Furthermore, if the constrained diameter of that IS 10 as shown in Fig. 2 is less than the free diameter of the coil spring IS 10, then additional dilation may occur following the insertion of the IS 10. Furthermore, if the intima layer was torn-(i.e dissected) during balloon dilation, the IS 10 can hold that intima layer in place and prevent subsequent blockage of the artery which can result from the effect of blood flow causing the torn intima to come off the wall of the dilated stenosis.

Fig. 3 shows the distal end of the insertion catheter 20 which consists of an inner core 22 and an outer cylinder 24. The core 22 has a rounded and tapered front end 23 and helical grooves 26 into which the coil spring IS 10 is placed. The core 22 has a back groove 28 which contains the most proximal coil of the coil spring IS 10 which is prevented from springing radially outward by the flange 30.

Fig. 4 is a cross-sectional view of the proximal end of the insertion catheter 20. A cylindrically shaped cylinder handle 32 is molded onto the outer cylinder 24. A cylindrically shaped cylinder handle 32 is molded onto the outer cylinder 24. Similarly, a cylindrically shaped core handle 36 is molded onto the core 22. A conically shaped interior surface 34 of the cylinder handle 32 is used to help guide the cylinder handle 32 over the IS 10 as it is mounted on the distal end of the insertion catheter 20. The distance D in Fig. 4 is initially set to be slightly greater than the length of the IS 10 at the distal end of the insertion catheter 20.

The spring IS 10 is loaded onto the distal end of the core in the following manner:

1. A pair of pliers is used to hold the most distal portion of the IS 10 into the most distal spiral groove 26 of the inner core 22.
2. The spring IS 10 is then pulled and twisted applying torque to its most proximal end so that the spring IS 10 is forced into the helical grooves 26.
3. A pliers wide enough to hold all turns of the IS 10 in place except the most proximal turn and the most distan turn is then applied at the center of the IS 10 to hold it in the helical grooves 26.
4. A needle nose pliers is then used to force the most proximal turn of the IS 10 into the core groove 28.
5. The conical interior surface 34 of the cylindrical handle 32 is then fed over the most distal turn of the IS 10 as it sits in the most distal groove 26 of the core 22.
6. As the handle 32 is moved in the proximal direction, the broad pliers holding the central

portion of the IS 10 in place is simultaneously moved in the proximal direction until the entire IS 10 is covered by the interior surface of the handle 32 and the outer cylinder 24.

7. The handle 32 is then pulled in a proximal direction until the distal end of the cylinder 24 lies just over the last turn of the IS 10 which occurs when the cylinder handle 32 and the core handle 36 are separated by a distance D as shown in Fig. 4.

In this manner, a coil spring IS 10 whose unrestrained (i.e., free) diameter can be between 1.1 to 5.0 times larger than its diameter when stored on the core 22 can be placed at the distal end of the insertion catheter 20.

Deployment of the spring IS 10 within a recently dilated occlusion is accomplished in the following steps:

1. By conventional means, a guiding catheter (not shown) is placed percutaneously into the femoral artery and its distal end is advanced to the site where the IS 10 is to be released.

2. Under fluorscopic control, the insertion catheter 20 is advanced through the guiding catheter until the center of the IS 10 is positioned at the center of the recently dilated stenosis.

3. While holding the core handle 36 firmly against the body so that it does not move, the outer cylinder handle 32 is moved proximally so as to decrease to zero the distance D of Fig. 4.

4. All turns of the IS 10 except the most proximal turn are then expanded outward to engage the interior surface of the recently dilated stenosis.

5. The core 22 and the outer cylinder 24 are then pulled out of the body together which leaves the coil spring IS 10 in its desired place in the artery.

An angioplasty balloon could then be expanded within the IS 10 so as to more firmly imbed the spring into the stenotic plaque. The balloon and guiding catheters would of course be removed from the body after they were used for their intended purposes.

The coil spring used in this manner would:

1. Prevent restenosis of the occlusion.

2. Increase the lumen diameter by constantly applying an outward radial force to the plaque, and

3. Hold in place any intima layer torn from the stenosis during balloon dilation which might otherwise tend to block blood flow in that artery.

The materials of the core 22, core handle 36, outer cylinder 24 and outer cylinder handle 32 might be PVC or some other comparatively strong plastic. The IS 10 might be fabricated from a stainless spring steel or an alloy of titanium such as Ti-6Al-4V. The outside diameter of the unrestrained coil spring IS 10 might vary from 2 to 12mm depending on the lumen diameter into which it is implanted. The wire diameter might he between 0.1 and 0.5mm. The outer diameter of the outer cylinder 24 would be less than 4mm. The length of the IS 10 would be between 5 and 25mm depending upon the length of the dilated stenosis into which it would be placed.

Decreased thrombogenicity can be achieved by coating the outside of the coil with a non-thrombogenic material such as ULTI carbon. An enlarged cross section of such a sire is shown in Fig. 4. The metallic core is shown as 40 and the coating is shown as 42. Coating thickness might be as thin as 0.01mm or as thick as o.1mm.

Fig. 5 shows another enlarged cross section of the wire of the IS 10 in which the metallic core 40 is first covered by a plastic layer 44 such as PTFE and then coated with a non-thrombogenic coating 46 such as ULTI carbon. The plastic coating would typically be between 0.05 and 0.5mm and the non-thrombogenic coating might have a thickness between 0.01 and 0.5mm.

Although this intravascular stent might find its greatest application as a means to enhance balloon angioplasty in humans it could also be used to successfully provide permanent dilation and patency of other ducts and vessels within a living human or animal body. For example, this coil spring intravascular stent 10 could also be used to maintain long term patency of ureters or fallopian tubes. In every use, the fact that wire diameter would be typically 1/10 the coil spring pitch length i.e., only 10% of the lumen interior surface is actually in contact with a foreign material. Therefore, normal body cells could grow over the coils of such springs. Thus, the normal characteristics of the interior lining of such ducts or vessels would be only minimally compromised.

Various other modifications, adaptations, and alternative designs are, of course, possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

Claims

1. A stent insertion apparatus (20) having an inner core member (22) defining distal and proximal ends, a hollow outer sheath cylinder (24) defining distal and proximal ends and having an inner surface slidably mounted around and movable relative to said inner core member (22) characterized by:

a helical groove formed within an outer surface of said inner core member (22) extending from said distal end to said proximal end of

said inner core member (22) said groove receiving a coil stent (10), said hollow outer sheath cylinder (24) being movable relative to said inner core member (22) from a first position covering said helical groove (26) to a second position exposing said helical groove (26) wherein cooperation of said helical groove (26) of said inner core member (22) with said inner surface of said hollow sheathing cylinder (24) forms a helical cavity adapted to contain said coil stent (10) when said outer sheath cylinder (24) is in said first position, whereby said coil stent (10) is held in a radially compressed state within said helical cavity by exerting a radial outward force on said outer sheath cylinder (24) when said outer sheath cylinder (24) is in its first position and is released from said helical cavity and radially expandable by its intrinsic mechanical properties to a larger diameter when said outer sheath cylinder (24) is moved to said second position without the requirement of relative axial rotation between said inner core member (22) and said outer sheath cylinder (24).

2. The apparatus (20) of claim 1, wherein said inner core member (22) further comprises a flange means, adapted to frictionally engage the proximal end of said coil stent (10).

3. The apparatus of claim 2, wherein said flange means comprises:

a back groove (28) cut into the surface of said inner core member (22) and adapted to contain the proximal end of said coil stent (10); and,

a flange (30) located adjacent to said back groove (28) and adapted to prevent radial movement of said coil stent (10) which is frictionally engaged.

4. The apparatus (20) of Claim 1, wherein said inner core member (22) comprises a rounded and tapered distal end (23).

5. The apparatus (20) of claim 1, further comprising a control means of moving the distal end of said sheathing cylinder (24) from said first position to said second position relative to the distal end of said inner core member (22) and deploying said coil stent (10) without the requirement of axial rotation of the outer sheathing cylinder (24) relative to the inner core member (22).

6. The apparatus (20) of claim 5, wherein the proximal end of said sheathing cylinder (24) and said inner core member (22) extend external to said living body, and wherein said control means comprises a first handle (32) operably coupled to a proximal portion of said sheathing cylinder (24), and a second handle (36) operably coupled to a proximal portion of said inner core member (22), wherein movement of said first handle (32) toward said second handle (36) causes movement of the distal ends of said sheathing cylinder (24) from said first position to said second position relative to said inner core member (22) so as to release said coil stent (10).

Patentansprüche

1. Spannspiralen-Einsetzvorrichtung (20) mit einem inneren Kern (22), der ein distales und ein proximales Ende besitzt, einem hohlen äußeren Schutzzylinder (24), der ein distales und ein proximales Ende besitzt und mit einer inneren Oberfläche, die gleitfähig um den inneren Kern (22) herum und beweglich in Bezug auf diesen angebracht ist, **dadurch gekennzeichnet,** daß:

eine spiralförmige Nut, die in einer Außenfläche des inneren Kerns (22) ausgebildet ist, sich vom distalen Ende zum proximalen Ende des inneren Kerns (22) erstreckt, die Nut eine Spannspirale (10) aufnimmt, der hohle äußere Schutzzylinder (24) in Bezug auf den inneren Kern (22) von einer ersten Position, in der die spiralförmige Nut (26) überdeckt ist, zu einer zweiten Position, in der die spiralförmige Nut (26) freigegeben wird, bewegbar ist, wobei das Zusammenwirken der spiralförmigen Nut (26) des inneren Kerns (22) mit der Innenfläche des hohlen Schutzzylinders (24) einen spiralförmigen Hohlraum bildet, der die Spannspirale (10) aufnehmen kann, wenn sich der äußere Schutzzylinder in der ersten Position befindet, wodurch die Spannspirale (10) durch Ausüben einer radial nach außen gerichteten Kraft auf den äußeren Schutzzylinder (24), wenn sich dieser in seiner ersten Position befindet, in einem radial komprimierten Zustand im spiralförmigen Hohlraum gehalten wird und aus dem spiralförmigen Hohlraum freigegeben wird und durch seine mechanischen Eigenschaften auf einen größeren Durchmesser radial dehnbar ist, wenn der äußere Schutzzylinder (24) zu einer zweiten Position bewegt wird, ohne daß eine relative axiale Rotationsbewegung zwischen dem inneren Kern (22) und dem äußeren Schutzzylinder erfolgen muß.

2. Vorrichtung nach Anspruch 1, in der der innere Kern (22) weiterhin einen Flansch umfaßt, der das proximale Ende der Spannspirale (10) in

einer Reibschlußverbindung aufnehmen kann.

3. Vorrichtung nach Anspruch 2, in der der Flansch umfaßt:

eine rückwärtige Nut (28), geschnitten in die Oberfläche des inneren Kerns (22) und so ausgeführt, daß sie das proximale Ende der Spannspirale (10) aufnehmen kann und

einen Flansch (30) angeordnet neben der rückwärtigen Nut (28) und so ausgeführt, daß eine radiale Bewegung der Spannspirale (10), die sich im Reibungs-Eingriff befindet, verhindert wird.

4. Vorrichtung (20) nach Anspruch 1, in der der innere Kern (22) ein abgerundetes und kegelförmiges Ende (23) besitzt.

5. Vorrichtung (20) nach Anspruch 1, weiterhin bestehend aus Steuerungsmitteln für die Bewegung des distalen Endes des Schutzzylinders (24) von der ersten Position zur zweiten Position relativ zum distalen Ende des inneren Kerns (22) und für das Aufspannen der Spannspirale (10) ohne daß eine axiale Drehbewegung des äußeren Schutzzylinders (24) in Bezug auf den inneren Kern (22) stattfinden muß.

6. Vorrichtung (20) nach Anspruch 5, in der das proximale Ende des Schutzzylinders (24) und des inneren Kerns (22) sich außerhalb des Lebewesens befinden und bei der die Steuerungsmittel eine erste Handhabungseinrichtung (32) umfassen, manipulierbar mit dem proximalen Teil des Schutzzylinders (24) verbunden und eine zweite Handhabungseinrichtung (36), manipulierbar mit dem proximalen Teil des inneren Kerns (22) verbunden, wobei die Bewegung der ersten Handhabungseinrichtung (32) hin zur zweiten Handhabungseinrichtung (36) eine Bewegung der distalen Enden des Schutzzylinders (24) aus der ersten Position in die zweite Position relativ zum inneren Kern (22) bewirkt und damit die Spannspirale (10) freigegeben wird.

Revendications

1. Appareil pour l'introduction d'un distendeur (20) ayant un élément de noyau intérieur (22) définissant des extrémités distales et proximales, un cylindre de gaine extérieur creux (24) définissant des extrémités distales et proximales et ayant une surface intérieure qui est montée autour en pouvant coulisser et étant mobile par rapport à l'élément de noyau intérieur (22) mentionné, caractérisé par :
une rainure hélicoïdale formée à l'intérieur d'une surface extérieure de l'élément de noyau intérieur (22) mentionné qui s'étend de ladite extrémité distale vers ladite extrémité proximale de l'élément de noyau intérieur (22) mentionné, ladite rainure recevant un distendeur à ressort (10), ledit cylindre de gaine extérieur creux (24) étant mobile par rapport à l'élément de noyau intérieur (22) mentionné d'une première position qui couvre ladite rainure hélicoïdale (26) vers une seconde position exposant ladite rainure hélicoïdale (26) dans laquelle la coopération de ladite rainure hélicoïdale (26) de l'élément de noyau intérieur (22) mentionné avec ladite surface intérieure du cylindre de gaine creux (24) mentionné forme une cavité hélicoïdale adaptée pour contenir ledit distendeur à ressort (10), lorsque ledit cylindre de gaine extérieur (24) est dans ladite première position, ledit distendeur à ressort (10) étant maintenu dans un état comprimé radialement à l'intérieur de ladite cavité hélicoïdale en exerçant une force extérieure radiale sur ledit cylindre de gaine extérieur (24), lorsque ledit cylindre de gaine extérieur (24) est dans sa première position et est relâché de ladite cavité hélicoïdale et est extensible radialement grâce à ses propriétés mécaniques intrinsèques pour prendre un diamètre plus grand lorsque ledit cylindre de gaine extérieur (24) est déplacé dans ladite seconde position sans qu'il soit nécessaire qu'il y ait une rotation axiale relative entre ledit élément de noyau intérieur (22) et ledit cylindre de gaine extérieur (24).

2. Appareil (20) selon la revendication 1, dans lequel ledit élément de noyau intérieur (22) comprend en plus un organe à bride adapté pour se mettre en prise par friction avec l'extrémité proximale du distendeur à ressort mentionné (10).

3. Appareil selon la revendication 2, dans lequel ledit organe à bride comprend : une rainure arrière (28) taillée dans la surface de l'élément de noyau intérieur (22) mentionné et adaptée pour contenir l'extrémité proximale du distendeur à ressort mentionné (10) et
une bride (30) située en étant adjacente à ladite rainure arrière (28) et adaptée pour empêcher le mouvement radial du distendeur à ressort (10) mentionné qui est en prise par friction.

4. Appareil (20) selon la revendication 1, dans lequel ledit élément de noyau intérieur (22) comprend une extrémité distale (23) arrondie et conique.

5. Appareil (20) selon la revendication 1, comprenant en plus un organe de commande du déplacement de l'extrémité distale du cylindre de gaine (24) mentionné de ladite première position vers ladite seconde position par rapport à l'extrémité distale de l'élément de noyau intérieur (22) mentionné et du déploiement du distendeur à ressort (10) mentionné sans qu'il soit nécessaire qu'il y ait une rotation axiale du cylindre de gaine extérieur (24) par rapport à l'élément de noyau intérieur (22).

6. Appareil (20) selon la revendication 5, dans lequel l'extrémité proximale du cylindre de gaine (24) mentionné et ledit élément de noyau intérieur (22) s'étendent à l'extérieur du corps humain mentionné et dans lequel ledit organe de commande comprend une première poignée (32) couplée opérationnellement à une portion proximale du cylindre de gaine mentionné (24) et une seconde poignée (36) couplée opérationnellement à une portion proximale de l'élément de noyau intérieur (22) mentionné, dans lequel le mouvement de ladite première poignée (32) vers ladite seconde poignée (36) provoque le mouvement des extrémités distales du cylindre de gaine (24) mentionné de ladite première position à ladite seconde position par rapport à l'élément de noyau intérieur mentionné (22) de manière à relâcher ledit distendeur à ressort (10).

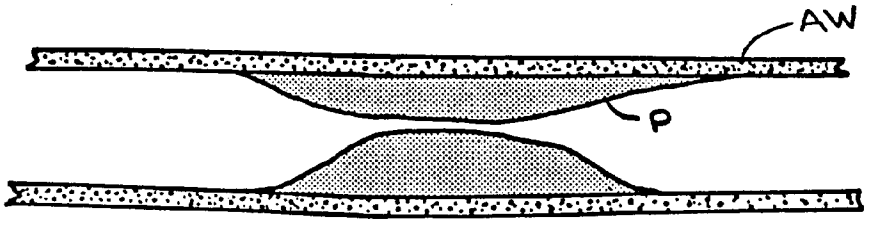


FIG. 1A

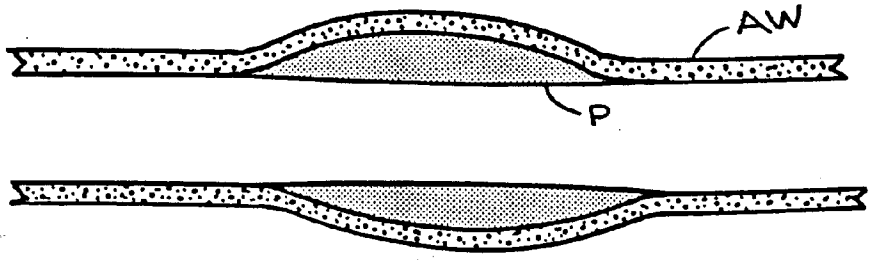


FIG. 1B

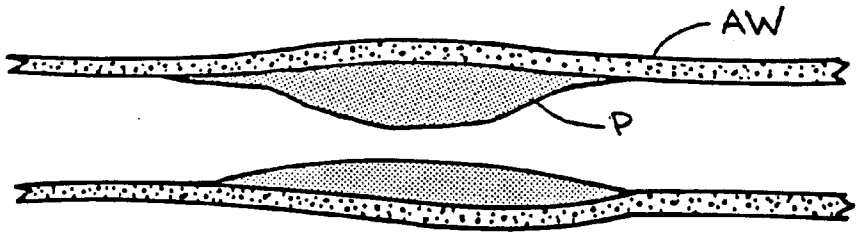


FIG. 1C

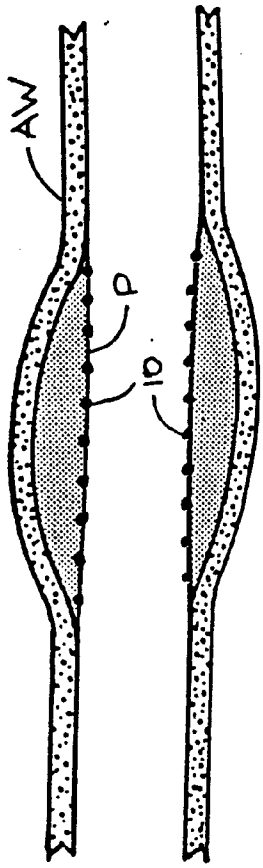


FIG. 2

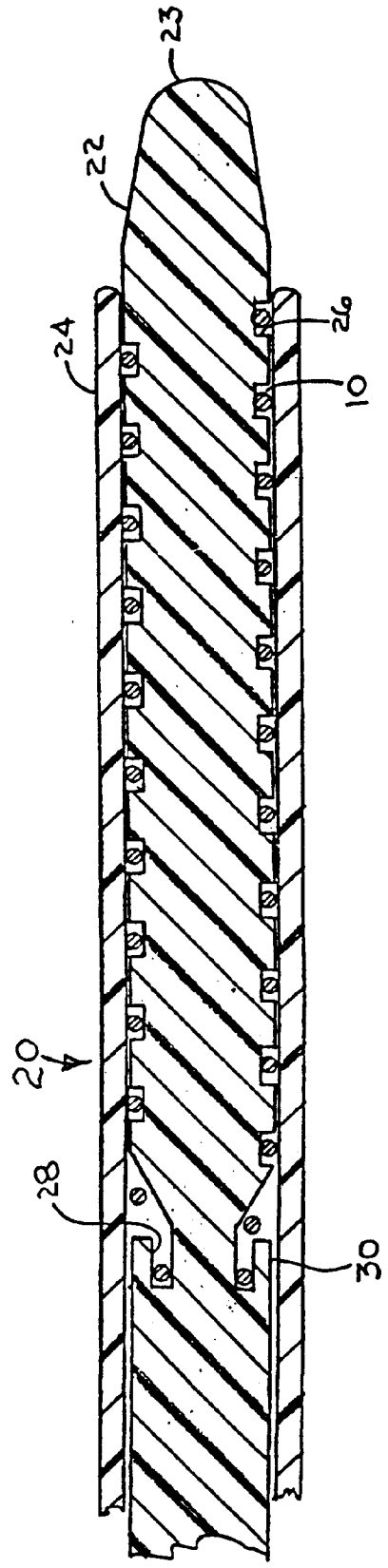
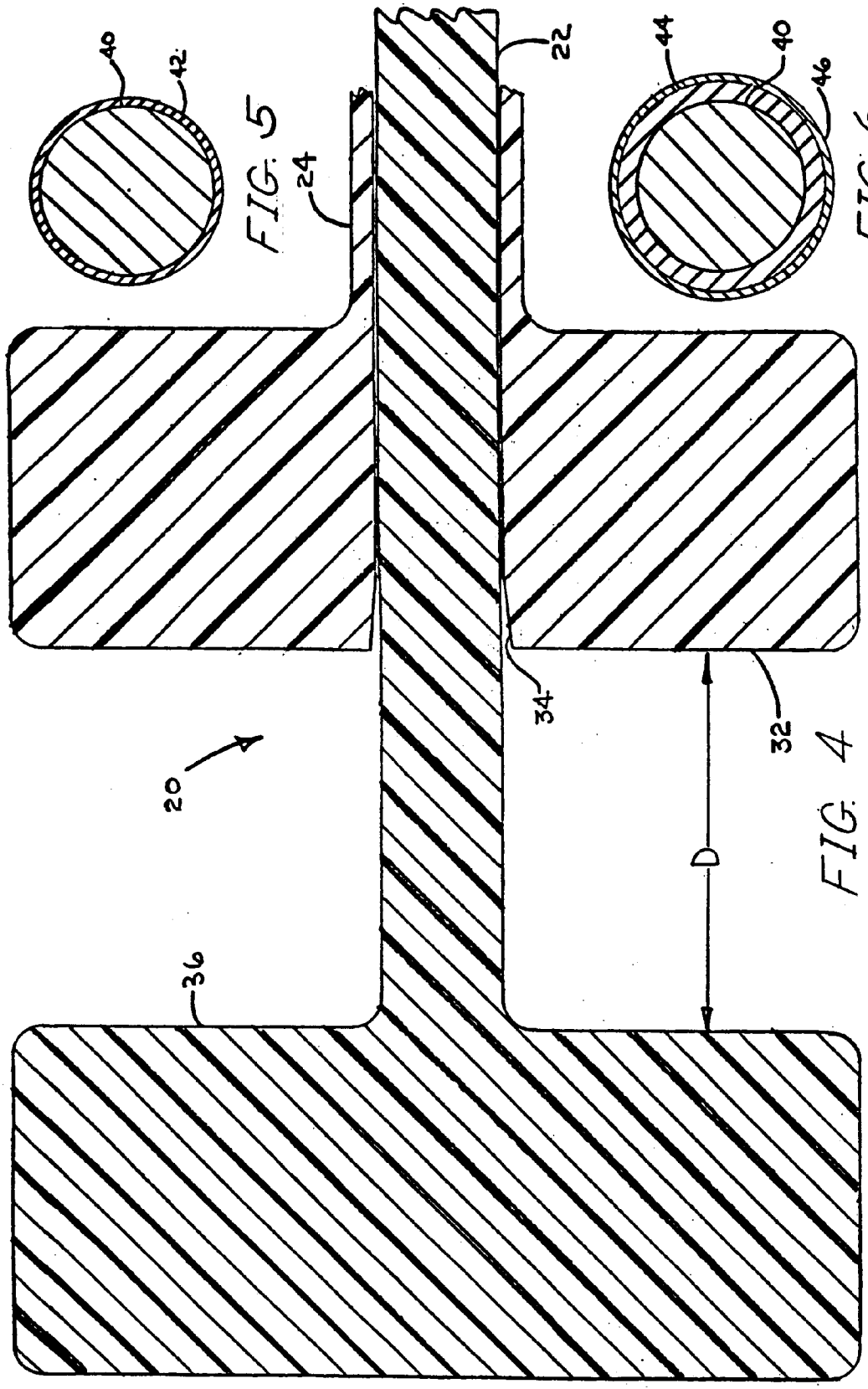


FIG. 3


40
42
FIG. 5
22
24
44
40
46
FIG. 6
20
34
32
D
FIG. 4
36